§ 111.83 What are the requirements for reserve samples?

- (a) You must collect and hold reserve samples of each lot of packaged and labeled dietary supplements that you distribute.
 - (b) The reserve samples must:
- (1) Be held using the same containerclosure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which it is distributed for packaging and labeling elsewhere;
- (2) Be identified with the batch, lot, or control number;
- (3) Be retained for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve sample, for use in appropriate investigations; and
- (4) Consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the dietary supplement meets product specifications.

§111.87 Who conducts a material review and makes a disposition decision?

Quality control personnel must conduct all required material reviews and make all required disposition decisions.

- §111.90 What requirements apply to treatments, in-process adjustments, and reprocessing when there is a deviation or unanticipated occurrence or when a specification established in accordance with §111.70 is not met?
- (a) You must not reprocess a rejected dietary supplement or treat or provide an in-process adjustment to a component, packaging, or label to make it suitable for use in the manufacture of a dietary supplement unless:
- (1) Quality control personnel conduct a material review and make a disposition decision to approve the reprocessing, treatment, or in-process adjustment; and

- (2) The reprocessing, treatment, or in-process adjustment is permitted by §111.77;
- (b) You must not reprocess any dietary supplement or treat or provide an in-process adjustment to a component to make it suitable for use in the manufacture of a dietary supplement, unless:
- (1) Quality control personnel conduct a material review and make a disposition decision that is based on a scientifically valid reason and approves the reprocessing, treatment, or in-process adjustment; and
- (2) The reprocessing, treatment or inprocess adjustment is permitted by §111.77;
- (c) Any batch of dietary supplement that is reprocessed, that contains components that you have treated, or to which you have made in-process adjustments to make them suitable for use in the manufacture of the dietary supplement must be approved by quality control personnel and comply with §111.123(b) before releasing for distribution.

§ 111.95 Under this subpart E, what records must you make and keep?

- (a) You must make and keep records required under this subpart E in accordance with subpart P of this part.
- (b) Under this subpart E, you must make and keep the following records:
 - (1) The specifications established;
- (2) Documentation of your qualification of a supplier for the purpose of relying on the supplier's certificate of analysis;
- (3) Documentation for why meeting in-process specifications, in combination with meeting component specifications, helps ensure that the dietary supplement meets the specifications for identity, purity, strength, and composition; and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement; and
- (4) Documentation for why the results of appropriate tests or examinations for the product specifications selected under §111.75(c)(1) ensure that the dietary supplement meets all product specifications;